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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/812,201      | 03/29/2004  | Palpu Pushpangadan   | 227981              | 1395             |

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EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/812,201 | <b>Applicant(s)</b><br>PUSHPANGADAN ET AL. |  |
|                              | <b>Examiner</b><br>Susan D. Coe      | <b>Art Unit</b><br>1655                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-8,11,14,27,28 and 37 is/are allowed.
- 6) ☒ Claim(s) 2,3,9,10,12,13,15-26 and 29-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The amendment filed October 20, 2005 has been received and entered.
2. In view of the prior art search, the restriction requirement of July 18, 2005 is withdrawn.
3. Claims 1-37 are examined on the merits.

### ***Oath/Declaration***

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The full name of the sixth inventor (family name and at least one given name together with any initial) has not been set forth.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating gastrointestinal ailments, does not reasonably provide enablement for curing these ailments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of

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working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to "cure" gastrointestinal ailments. In order to be enabled for curing a condition, applicant must demonstrate that the invention is able to cure the condition in each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to cure gastrointestinal problems for all potential causes of gastrointestinal problems. Thus, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the curing of gastrointestinal ailments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 9, 10, 12, 13, 15-26, and 29-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 2 is indefinite because "anti-spasmodic" is not a gastro-intestinal disorder.
7. Claim 3 is indefinite because it is unclear what amounts are encompassed by "high antioxidant."
8. Claim 9 is rendered indefinite by the use of parentheses. It is unclear if the enclosed limitations are a required part of the claim.

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9. Claims 12 and 25 are rendered indefinite by the phrase “wherein the lubricants used are from starch and lactose.” It is unclear if applicants intend for the lubricants to be selected from either starch or lactose or if the lubricant is a substance derived from starch or lactose and what these substances could be.

10. Claim 13 is indefinite because the phrase “the 66.7% w/w sugar syrup” lacks antecedent basis.

11. Claim 15 is indefinite because the phrase “the part,” in line 3, lacks antecedent basis. Claim 15 is also indefinite because it is unclear what powder sizes are encompassed by “coarse.” In addition, this claim is indefinite because it is unclear what the phrase “the plant material” in step e is referring to. Are there two extractions performed, one in step d and one in step e? If this is so, it is unclear what is extracted in step e because “the plant material” is unclear.

12. Claim 16 is indefinite because it conflicts with claim 15. Claim 15 requires that all of *Mangifera indica*, *Cissampelos pareira*, *Buchanania lanzan*, and *Cinnamomum* sp. be present in the composition. Claim 16 states that the plant used in the extraction method is “selected from a group comprising” these plants. This conflict is confusing and improper. In addition, the use of the phrase “a group comprising” is indefinite because it is not clear if unrecited elements are part of the Markush group.

13. Claim 17 is indefinite because it refers to “the extraction” in step b. Step b is a drying step, not an extraction step.

14. Claim 18 is indefinite because it does not recite all four of the plants required in claim 15. Does this indicate that all four are not required? If this is so, this conflict is indefinite and improper.

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15. Claim 22 is indefinite because it refers to the alcohol used in step f. Step f is a concentration step that does not use an alcohol. This conflict is confusing.
16. Claims 10, 23 and 29 are indefinite due to the use of "a group comprising." This is improper Markush language.
17. Claims 30-36 are indefinite because the phrase "the applied dosage" lacks antecedent basis.
18. Claim 30 is indefinite because it is unclear how the percent protection is measured.
19. Claim 31 is indefinite because it is unclear how the curative percent is measured.
20. Claim 32 is indefinite because it is unclear how fluid accumulation is measured.
21. Claims 33 and 34 indefinite because it is unclear what "the concentration of sodium" and "the concentration of potassium" are referring to. Does this mean the concentration of sodium or potassium in the accumulated fluid?
22. Claim 35 is indefinite because it is unclear how the protection percentage is measured. In addition, it is unclear what is encompassed by a "significant increase."
23. Claim 36 is indefinite because it is not clear what is meant by "shows a 41.7 to 90.2 incidence (treated)...".

### ***Conclusion***

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Puri et al. Journal of Ethnopharmacology (2000), vol. 71, pp. 89-92; Singh et al. Journal of Ethnopharmacology (2002), vol. 81, pp. 31-41; and Heinrich, Phytotherapy Research (2000), vol. 14, pp. 479-488.

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25. All claims are considered free of the prior art. Claims 1, 4-8, 11, 14, 27, 28, and 37 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



10-31-05

Susan D. Coe  
Primary Examiner  
Art Unit 1655